UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,904	10/14/2003	Peter M. Bonutti	780-A03-012B	3567

33771 7590 12/03/2009
PAUL D. BIANCO
Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER	
HOFFMAN, MARY C	
ART UNIT	**PAPER NUMBER**
3733	
MAIL DATE	**DELIVERY MODE**
12/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/684,904	**Applicant(s)** BONUTTI, PETER M.
	Examiner MARY HOFFMAN	**Art Unit** 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _09/18/2009_.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1,3-46 and 51-67_ is/are pending in the application.
4a) Of the above claim(s) _63-67_ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1, 3-46, 51-62_ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on _14 October 2003_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _see "Other"_.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: _4/6/09, 4/6/09, 6/18/09, 9/18/09, 9/22/09, 10/6/09_.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2009 has been entered.

Election/Restrictions

Applicant's election with traverse of the restriction requirement in the reply filed on 9/18/2009 is acknowledged. The traversal is on the ground(s) that claims 63 add additional elements to the method, and contain all the subject matter of the original claims. This is not found persuasive because claims 63-67 are drawn to different methods that do not contain the same base method steps, and searching for claims 63-67 would put a substantial burden on the examiner. For example, the previous claims require the step of offsetting the patella, whereas claims 63-67 do not.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 10 -11, 28, and 31, 34, 35, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonnell et al. (U.S. Patent No. 4,203,444). See evidentiary patent to Trott, U.S. Patent No. 4,646,738

Bonnell et al. disclose a method of performing a knee arthroplasty surgery on a leg of a patient, comprising making an incision in a knee portion of the leg having a length not more than 13 cm (see small puncture wound, FIG. 2); displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward (col. 3, line 23); and positioning a cutting tool (ref. #10) proximal to at least one of an upper or a lower portion of the leg and cutting bone of the leg while the patella is maintained offset from a normal position and not everted. The method further comprising cutting an end surface of at least one of the upper or lower portions of the leg (col. 1, line 65-col 2, line 1). The method further comprising connecting a guide member (FIG. 2, ref. #14) to at least one of the upper or lower portions of the leg. The incision in the knee portion of the leg comprises making the incision adjacent to a medial edge portion of the patella.

Similarly, Bonnell et al. disclose a method of performing a knee arthroplasty surgery on a leg of a patient comprising making an incision in a knee portion of the leg having; displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and connecting a guide member to at least one of the upper or lower portions of the leg; wherein the guide member is connected to the lower portion of the leg, the lower portion being a tibia; cutting a bone of the knee portion of the leg, while the patella is maintained in the offset position, and while no bone of the knee extends to pass outside the patient's body through said incision, until cut and removed from the joint. The method further comprising cutting an end surface of the tibia.

Similarly, Bonnell et al. disclose a method of performing a knee arthroplasty surgery on a leg of a patient, comprising: making an incision in a knee portion of the leg, displacing a patella in the knee portion of the leg from a normal position to an offset position with an inner side of the patella facing inward; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; cutting the inner side of the patella in the knee portion of the leg, wherein the inner side of the patella faces towards a posterior portion of the knee portion of the leg and includes removing at least a portion of the inner side of the patella, while no bone of the joint extends to pass outside the body through said incision, until cut and removed from the joint; and wherein the inner side of the patella is cut prior to displacing the patella from the normal position to the offset position (The patella is only moved in Bonnell et al. when cutter ref. #10 can no longer cut the surface patella without manipulating the patella to be manipulated. Because of the curved surface of the patella, the patella will require some manipulation in order to treat the entire surface. See explanation of this in evidentiary patent to Trott, U.S. Patent No. 4,646,738, in its discussion of the Bonnell et al. prior art)

Similarly, Bonnell et al. disclose a method comprising: making an incision in a knee portion of the leg of the patient having a length not more than a distance between, about the proximal end of the tibia to about the epicondylar notch on the distal end portion of the femur; displacing the patella from the normal position to an offset position with an inner side of the patella facing inward; and cutting an inner side portion of a patella in the knee portion of the leg, the patella being maintained in the offset position. The method of further comprising positioning a cutting The method further comprising cutting an end surface of at least one of an upper and lower portions of the leg. tool proximal to at least one of the upper and lower portions of the leg. The inner side of the patella is cut prior to displacing the patella from the normal position to the offset position. Displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnell et al. (U.S. Patent No. 4,646,738) in view of Caspari (5,171,276).

Bonnell et al. disclose the claimed invention except for inserting implants.

Caspari discloses that knee implants can be advantageously placed under arthroscopic surgical techniques to treat the joint (col. 3, line 51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place knee implants under arthroscopy in view of Caspari to treat the joint.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnell et al. (U.S. Patent No. 4,646,738) in view of Whitt (U.S. Patent No. 4,373,709)

Bonnell et al. disclose the claimed invention except for supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position.

Whitt discloses a surgical limb holder that allows the surgeon to adjust the position of the knee during a surgical procedure. Fig. 1 of Whitt shows the lower portion of the leg suspended from the upper portion of the leg during the surgery. This device allows a great variety of sizes, positions, and attitudes so that the limb can be held in any position which will enhance and facilitate the surgery (col. 1. lines 19-21) and thus contemplates that a surgery may be performed with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position, if such position is determined by the surgeon to facilitate the surgery.

Therefore, it would have been obvious to perform the method of Bonnell et al. with supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position further in view of Whitt, since Whitt shows that the lower leg can be suspended during a surgery to facilitate and enhance the surgery.

Claims 1, 4-9, 16-17, 24-25, 28-46, 51-52 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314). Also see evidentiary patent to Caspari, Patent No. 5,395,376.

Johnson et al. disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position (see FIGS. 8-9); and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg and cutting bone of the leg while the patella is maintained offset from a normal position. The method further comprising cutting an end surface of at least one of the upper or lower portions of the leg. The method further comprising moving at least one implant through the incision while the patella is offset from the normal position; and connecting the at least one implant with the cut end portion of at least one of the upper or lower portions of the leg. The method further comprising connecting a guide member to at least one of the upper or lower portions of the leg (FIG 10). The guide member is connected to the upper portion of the leg, the upper portion being a femur, the guide member including a first end portion in engagement with a lateral condyle of the femur, the first end portion offset medially from a lateral edge portion of the lateral condyle, and a second end portion in engagement with a medial condyle of the femur, the second end portion offset laterally from a medial edge portion of the medial condyle. The method comprising cutting the lateral and medial condyle of the femur. The method further comprising cutting an end surface of the tibia. The method further comprising moving at least one tibial implant through the incision while the patella is offset from the normal position; and connecting the at least one tibial implant with the cut end portion of the tibia. The method further comprising initiating a cut with the cutting tool along an end portion of at least one of the upper or lower portions of the leg to define a cutting surface; and completing the cut while guiding the cutting tool along the cutting surface formed during making of the initial cut in an end portion of at least one of the upper or lower portions of the leg. Johnson et al. further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; exposing a first portion of the upper portion of the leg through the incision; effecting relative movement between the upper and lower portions of the leg; and exposing a second portion of the upper portion of the leg through the incision. Making the incision in the knee portion of the leg comprises making the incision adjacent to a medial edge portion of the patella. Johnson et al. further disclose a method of performing surgery on a leg of a patient, comprising: making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and wherein displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg. Johnson et al. further disclose a method of performing a knee arthroplasty surgery on a leg of a patient, comprising making an incision in a knee portion of the leg of the patient; cutting an inner side portion of a patella in the knee portion of the leg, the patella being disposed in a normal position relative to the knee portion of the leg; and displacing the patella from the normal position to an offset position. The method further comprising the steps of: forming an opening in a bone of the leg; and positioning a portion of an intramedullary alignment device within said opening, positioning an extramedullary alignment device proximate a bone of the leg. The method further comprising the steps of: sequentially passing portions of an implant through said incision; and, affixing at least two of said implant portions, one to the other, within the leg, in association with one side of the knee joint. The method further comprising the steps of: replacing at least a portion of a single condyle with an implant; and, replacing at least a portion of a trochlear groove with an implant. The cutting tool is fabricated at a lower cost than a reusable cutting tool by being designed to be used in a single procedure and thereafter discarded (product-by-process recitation).The method further comprising the step of: positioning said cutting tool proximal to a side surface of the distal end of the femur to guide cutting the bone of the leg.

Johnson et al. does not disclose cutting the bone while the patella is not everted (i.e. with the inner side of the patella facing inward), and does not disclose positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, and a patella implant, or the order that the steps are performed, and making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters.

Waddell discloses that the patella should not be everted and should remain facing inward during the cutting and positioning steps, including resection of the patella (column 8, lines 14-15) in order to decrease the failure of total knee arthroplasty (col. 2, lines 63-67 and col. 3, lines 1-8), and Waddell teaches an improved patella guide assembly and method, including positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, to achieve accurate placement and functioning of the resection patella (Abstract). Waddell also discloses a patella implant as part of knee arthroplasty

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. including not everting the patella and including placing a guide assembly proximal the patella and inserting a patella implant in view of Waddell to decrease the chance of failure of the surgery and to achieve accurate placement and functioning of the resection patella. It would have further been obvious to perform the steps in various orders according to common sense, as long as the different order does not affect the overall method.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. in view of Waddell making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, the desirability of minimally invasive incisions, i.e. smaller incisions, was well known in the surgical arts, since smaller incisions correspond to lower risks of complications such as infection. Applicant is referred to Caspari, evidentiary Patent No. 5,395,376, which recommends a reduced size incision (ref. #280) of one to one-half inch, showing that it was known in the prior art that reduced sized incisions were desirable

Regarding claim 57, Johnson et al. in view of Waddell further discloses the claimed invention except for the implant including a plurality of layers, at least one of said layers including at least one material selected from the group consisting of: fetal cells, bone cells, embryonal cells, stem cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Johnson et al. in view of Waddell out of fetal cells, bone cells, embryonal cells, stem cells, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Howell (U.S. Patent No. 6,019,767).

Johnson et al. in view of Waddell discloses the claimed invention except for the expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision.

Howell discloses expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision (see FIGS. 7-8) to expand the surgical incision to allow the surgeon to see surgical site.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. in view of Waddell including expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision in view of Howell to expand the surgical incision to allow the surgeon to see surgical site.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709)

Johnson et al. in view of Waddell further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg. Johnson does not disclose supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position. Johnson does show in Fig. 9 the lower leg being suspended.

Whitt discloses a surgical limb holder that allows the surgeon to adjust the position of the knee during a surgical procedure. Fig. 1 of Whitt shows the lower portion of the leg suspended from the upper portion of the leg during the surgery. This device allows a great variety of sizes, positions, and attitudes so that the limb can be held in any position which will enhance and facilitate the surgery (col. 1. lines 19-21) and thus contemplates that a surgery may be performed with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position, if such position is determined by the surgeon to facilitate the surgery.

Therefore, it would have been obvious to perform the method of Johnson in view of Waddell with supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position further in view of Whitt, since Whitt shows that the lower leg can be suspended during a surgery to facilitate and enhance the surgery.

Claims 22-23, 54-56 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Wang et al. (U.S. Patent No. 6,102,850).

Johnson et al. in view of Waddell discloses the claimed invention except for using an endoscope and robotics.

Wang et al. discloses using an endoscope and robotics to assist the surgeon (see Abstract)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. in view of Waddell to use endoscope and robotics in view of Wang et al. to assist the surgeon.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Gustilo (U.S. 5,733,292).

Johnson et al. in view of Waddell discloses the claimed invention except for using transducers.

Gustilo et al. disclose using transducers to provide information on forces within the joint.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. in view of Waddell to use transducers in view of Gustilo et al. to provide information on forces within the joint.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709).

Johnson et al. in view of Waddell discloses the claimed invention except for a supporting member including actuating and controlling means, operative to move the lower portion of the leg.

Whitt discloses using a supporting member including actuating and controlling means, operative to move the lower portion of the leg to hold the leg in the optimum position during surgery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Johnson et al. in view of Waddell using a supporting member including actuating and controlling means, operative to move the lower portion of the leg in view of Whitt to hold the leg in the optimum position during surgery.

Claims 1, 4-9, 13-18, 24-25, 28-46, 51-52 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,643,272) in view of Waddell (U.S. Patent No 6,174,314). Also see evidentiary patent to Caspari, Patent No. 5,395,376.

Haines et al. disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position (see FIG. 11); and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg and cutting bone of the leg while the patella is maintained offset from a normal position. The method further comprising cutting an end surface of at least one of the upper or lower portions of the leg. The method further comprising moving at least one implant through the incision while the patella is offset from the normal position; and connecting the at least one implant with the cut end portion of at least one of the upper or lower portions of the leg. The method further comprising connecting a guide member to at least one of the upper or lower portions of the leg (FIG 11). The guide member is connected to the upper portion of the leg, the upper portion being a femur, the guide member including a first end portion in engagement with a lateral condyle of the femur, the first end portion offset medially from a lateral edge portion of the lateral condyle, and a second end portion in engagement with a medial condyle of the femur, the second end portion offset laterally from a medial edge portion of the medial condyle. The method further comprising moving a guide member into the incision, the guide member including opposite ends spaced apart by a distance which is less than a distance between a lateral epicondyle and a medial epicondyle on a femur; positioning the guide member on the femur in the leg of the patient with the opposite ends of the guide member aligned with an axis through the lateral and medial epicondyles; positioning the cutting tool on the guide member; and moving the cutting tool along a guide surface on the guide member to cut the lateral and medial epicondyles on the femur. The method comprising cutting the lateral and medial condyle of the femur. The method further comprising cutting an end surface of the tibia. The method further comprising moving at least one tibial implant through the incision while the patella is offset from the normal position; and connecting the at least one tibial implant with the cut end portion of the tibia. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position. The method further comprising initiating a cut with the cutting tool along an end portion of at least one of the upper or lower portions of the leg to define a cutting surface; and completing the cut while guiding the cutting tool along the cutting surface formed during making of the initial cut in an end portion of at least one of the upper or lower portions of the leg. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; exposing a first portion of the upper portion of the leg through the incision; effecting relative movement between the upper and lower portions of the leg; and exposing a second portion of the upper portion of the leg through the incision. Making the incision in the knee portion of the leg comprises making the incision adjacent to a medial edge portion of the patella. Making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising: making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and wherein displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg. Haines et al. further disclose a method of performing a knee arthroplasty surgery on a leg of a patient, comprising making an incision in a knee portion of the leg of the patient; cutting an inner side portion of a patella in the knee portion of the leg, the patella being disposed in a normal position relative to the knee portion of the leg; and displacing the patella from the normal position to an offset position. The method further comprising the steps of: sequentially passing portions of an implant through said incision; and, affixing at least two of said implant portions, one to the other, within the leg, in association with one side of the knee joint. The method further comprising the steps of: replacing at least a portion of a single condyle with an implant; and, replacing at least a portion of a trochlear groove with an implant. The cutting tool is fabricated at a lower cost than a reusable cutting tool by being designed to be used in a single procedure and thereafter discarded (product-by-process recitation).The method further comprising the step of: positioning said cutting tool proximal to a side surface of the distal end of the femur to guide cutting the bone of the leg.

Haines et al. does not explicitly state whether the patella is everted (i.e. with the inner side of the patella facing inward), and does not disclose positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, and inserting a patella implant, and the order of the steps is not specifically disclosed, and making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters.

Waddell discloses that the patella should not be everted and should remain facing inward during the cutting and positioning steps, including resection of the patella (column 8, lines 14-15) in order to decrease the failure of total knee arthroplasty (col. 2, lines 63-67 and col. 3, lines 1-8), and Waddell teaches an improved patella guide assembly and method, including positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, to achieve accurate placement and functioning of the resection patella (Abstract). Waddell also discloses a patella implant as part of knee arthroplasty

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. including not everting the patella and including placing a guide assembly proximal the patella and inserting a patella implant in view of Waddell to decrease the chance of failure of the surgery and to achieve accurate placement and functioning of the resection patella. It would have further been obvious to perform the steps in various orders according to common sense, as long as the different order does not affect the overall method.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Haines et al .in view of Waddell making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters (i.e. not more than 13 centimeters), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, the desirability of minimally invasive incisions, i.e. smaller incisions, was well known in the surgical arts, since smaller incisions correspond to lower risks of complications such as infection. Applicant is referred to Caspari, evidentiary Patent No. 5,395,376, which recommends a reduced size incision (ref. #280) of one to one-half inch, showing that it was known in the prior art that reduced sized incisions were desirable.

Regarding claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,643,272) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709)

Haines et al. in view of Waddell further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg;

displacing a patella in the knee portion of the leg from a normal position to an offset position; and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg. Johnson does not disclose supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position.

Whitt discloses a surgical limb holder that allows the surgeon to adjust the position of the knee during a surgical procedure. Fig. 1 of Whitt shows the lower portion of the leg suspended from the upper portion of the leg during the surgery. This device allows a great variety of sizes, positions, and attitudes so that the limb can be held in any position which will enhance and facilitate the surgery (col. 1. lines 19-21) and thus contemplates that a surgery may be performed with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position, if such position is determined by the surgeon to facilitate the surgery.

Therefore, it would have been obvious to perform the method of Haines et al. in view of Waddell with supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position further in view of Whitt, since Whitt shows that the lower leg can be suspended during a surgery to facilitate and enhance the surgery.

Regarding claim 57, Haines et al. in view of Waddell further discloses the claimed invention except for the implant including a plurality of layers, at least one of said layers including at least one material selected from the group consisting of: fetal cells, bone cells, embryonal cells, stem cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Haines et al. in view of Waddell out of fetal cells, bone cells, embryonal cells, stem cells, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Wang et al. (U.S. Patent No. 6,102,850).

Haines et al. in view of Waddell discloses the claimed invention except for the expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision.

Wang et al. discloses expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision (see FIGS. 7-8) to expand the surgical incision to allow the surgeon to see surgical site.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell including expanding the incision by applying a force against opposite edge portions of the incision with retractors, wherein the displacement of the patella from the normal position to the offset position is performed contemporaneously with the expanding of the incision (see FIGS. 7-8) in view of Wang et al. to expand the surgical incision to allow the surgeon to see surgical site.

Claims 22-23, 54-56 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Wang et al. (U.S. Patent No. 6,102,850).

Haines et al. in view of Waddell discloses the claimed invention except for using an endoscope and robotics.

Wang et al. discloses using an endoscope and robotics to assist the surgeon (see Abstract)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell to use endoscope and robotics in view of Wang et al. to assist the surgeon.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Gustilo (U.S. 5,733,292).

Haines et al. in view of Waddell discloses the claimed invention except for using transducers.

Gustilo et al. disclose using transducers to provide information on forces within the joint.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell to use transducers in view of Gustilo et al. to provide information on forces within the joint.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709).

Haines et al. in view of Waddell discloses the claimed invention except for a supporting member including actuating and controlling means, operative to move the lower portion of the leg.

Whitt discloses using a supporting member including actuating and controlling means, operative to move the lower portion of the leg to hold the leg in the optimum position during surgery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell using a supporting member including actuating and controlling means, operative to move the lower portion of the leg in view of Whitt to hold the leg in the optimum position during surgery.

Response to Arguments

Applicant's arguments filed 09/18/2009 have been fully considered but they are not persuasive.

Regarding claims 1, 23, 25-26, 30-31, 43, 64, 66-67, Applicant argues that the prior art does not disclose a reduced size incision, and therefore a reduced size incision would be unobvious. Applicant states that the incision disclosed by the prior art, the "well known prior art parapatellar incision (referred to in Waddell) was sufficiently long enough to enable complete exposure of the distal femur and proximal tibia, " is "inherently" longer than about twice the width of the patella or more than 13cm. The examiner respectfully disagrees. First, regarding the claim limitation stating 13cm, it is noted that depending on patient size, the length of the incision will vary. Therefore, for a young patient, the incision will be much smaller than the incision size for an adult. In addition, the examiner disagrees that the standard medial parapatellar incision of Waddell is inherently longer than about twice the width of the patella or more than 13cm. As evidenced by Patent No. 6,482,209 to Engh, the conventional incision for total knee replacement surgery can be 8 to 15 centimeters (see FIG. 2, col. 8, beginning at line 53), which is about twice the width of the patella. Engh states that this length of incision is large enough to expose the entire knee joint articular surfaces. Thus, Applicant's argument that an incision of 13cm or less is inherently too small to be able to expose the knee joint is not persuasive, since the Engh reference clearly shoes that an incision size of 8cm is sufficiently long t enable complete exposure of the joint.

Applicant further states that there was significant motivation to reduce the size of the incision but that the prior arts failure to do so is evidence of nonobviousness. See Applicant's discussion of the 37 C.F.R. 1.132 Declaration filed 5/9/2008 in related case 11/170969. It appears applicant is arguing that Applicant's method meets a long-felt need. However, Applicant's declaration is filed 5/9/2008 in related case 11/170969 insufficient to show a long-felt need. There is no evidence that the claimed subject matter solved a problem that was long standing in the art. Also, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem.

To show long felt need, the claimed invention must satisfy a long-felt need which was recognized, persistent, and not solved by others. It is noted that establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a "do-it-yourself" window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. "[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved".) Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971). See MPEP 716.04 for a full discussion of long-felt need.

Rather than establishing a long felt need, the declaration filed 5/9/2008 under 37 C.F.R. 1.132 in related case 11/170969 currently supports the examiner's assertion that there was significant motivation to reduce the incision size in the prior art because reduced incisions sizes are desirable; therefore, doing so would have been obvious. In addition, Applicant is referred to Patent No. 5,395,376, which recommends a reduced size incision (ref. #280) of one to one-half inch, showing that it was known in the prior art that reduced sized incisions were desirable.

Regarding claim 16, it would have further been obvious to perform the steps in various orders according to common sense, as long as the different order does not affect the overall method. It would be obvious to an orthopedic surgeon performing the surgery to rearrange the order of the steps of the methods, since in this case, cutting the patella prior to resecting the femur would not significantly change the overall methods of Johnson in view of Waddell, and Haines in view of Waddell.

Regarding claims 10, 19 and 21, Applicant's arguments have been considered and are deemed persuasive. See newly cited rejections above.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733